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Dated: August 16, 2011

Signature: /David A. Gass #38,153/  
(David A. Gass)

Docket No.: 28113/39467A  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Kari Alitalo et al.

Application No.: 10/567,630

Confirmation No.: 2853

Filed: May 30, 2006

Art Unit: 1634

Allowed: May 16, 2011

For: MATERIALS AND METHODS FOR  
COLORECTAL CANCER SCREENING,  
DIAGNOSIS, AND THERAPY

Examiner: S. T. Kapushoc

**APPLICATION FOR PATENT TERM  
ADJUSTMENT RECALCULATION UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Ladies and Gentlemen:

The Applicant requests that the U.S. Patent and Trademark Office (PTO) reconsider its calculation of Patent Term Adjustment (PTA) for the above-referenced application. The correct PTA will be in excess of the 206 days of PTA indicated in the preliminary calculation that accompanied the Notice of Allowance.

This Application is accompanied by \$200 in payment of the fee set forth in 37 CFR 1.18(e). Please charge any necessary but unpaid fees to Marshall, Gerstein & Borun LLP Deposit Account No. 13-2855 under order number 28113/39467A.

This paper is filed to request reconsideration of the Office's preliminary patent term adjust calculation, particularly as it relates to evaluation of "A Delay" and Applicant delay, which the Applicants calculate should be 883 days.

**I. Introduction**

"A Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt first and subsequent actions by the PTO. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than a three year application pendency.

**II. Applicants reserve the right to challenge "B Delay"**

The Office's PTA calculation that is shown on PAIR and that is reported with the allowance papers did not account for "B delay" to which this application will be entitled at the time of issuance. However, "B delay" analysis/calculation is not briefed here, because the Applicants acknowledge that the Office's practice is to ignore "B delay" at the time of allowance (and until the Office sets the exact issue date). The Applicants reserve the right to challenge an incorrect "B delay" calculation (or incorrect A/B overlap analysis) after issuance.

**III. The Office's Calculation of "A delay" was improper because it did not account for vacated actions.**

**A. Uncontested findings**

The Office calculated 37 days of "A delay" on account of a late mailing of the Notice of Allowance and 169 days of "A delay" on account of late mailing of a first action – a restriction requirement – on January 15, 2008. The Applicants do not dispute the 37-day calculation, but dispute the calculation of "A delay" based on the time of the first action tolling pursuant to 37 CFR 1.702(a)(1).

B. Contested findings relating to PTA pursuant to 37 CFR 1.702(a)(1)

This application is a US national filing of PCT/EP04/08819 (international filing date August 6, 2004), which claims priority benefit of a provisional application filed on August 8, 2003. Under 35 USC 371, national phase commenced on February 8, 2006, and all requirements of 37 CFR 371 were deemed complete by May 30, 2006, the filing date of the inventors' declaration. Thus, "A delay" pursuant to 37 CFR 1.702(a)(1) accrues from July 30, 2007 (14 months after national phase requirements were completed) until issuance of a first action.

As explained in detail below, the first action in this case issued on January 21, 2010. Based on this date, the "A delay" that should be awarded to the Applicant on account of a delayed first action is 906 days (from July 30, 2007, to January 21, 2010).

The Office incorrectly based its PTA calculation under 37 CFR 1.702(a)(1) on a restriction requirement dated January 15, 2008. Neither this restriction requirement, nor three more that followed it, are the proper "first action" for purposes of calculating PTA that accrued under 37 CFR 1.702(a)(1). The prosecution history demonstrates that the Office issued four improper restriction requirements (from January 15, 2008 to July 31, 2009), that were vacated. These erroneous restriction requirements were the subject of an interview between Applicant's representative Jennifer Flory and PTO practice specialist Julie Burke on August 28, 2009. The Office's interview summary dated September 2, 2009, confirms that the four restriction requirements were improper and would be replaced by a unity of invention analysis; that the four restriction requirements were *vacated by the Office*, and that ***no first action on the merits has been mailed out:***

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The four restriction requirements were discussed in view of the claims as pending. All four restriction requirements will be vacated and will be replaced with a new lack of unity determination which divides the claims as pending into 3 groups (method of detecting, method of treatment and method of screening for modulator) and sets forth several election of species requirements. Combination claims 15 and 54-55 would be examined with the elected subcombination, as appropriate, in view of ISPE Guidelines Example 10. Applicant requested that the Office mail out a written requirement to clarify the record and permit applicants to re-assess their election. Applicants are not bound by their previous election because no first action on the merits has been mailed out. The Office regrets the confusion and delay....

In a further interview summary dated November 23, 2009, the Office reiterated that the four restriction requirements from 2008-09 had been vacated and confirmed that these vacated actions **should not be used to calculate PTA**:

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant confirmed that they elected Group I, Claims 1-15 and 79, the Dominant negative prox 1, measuring Prox 1 expression level, beta catenin/TCF signaling pathway, nuclear localization of beta-catenin, wherein the inhibitor is a dominant negative Prox-1 encoding nucleic acid. The application will be transferred to 1630s workgroup for preparation of a first office action on the merits.

The restriction requirements mailed on 1/15/08, 8/19/08, 12/10/08 and 7/31/09 have been vacated from the record and should not be used to calculate applicants Patent Term Adjustment. .

Thus, Office personnel have already determined that the first action in this case, for PTA purposes under 37 CFR 1.702(a)(1), was not issued until the action following the aforementioned interview summaries. That action was mailed on January 21, 2010.

#### **IV. Applicant delay**

The Office calculated an Applicant delay of 163 days. However, only 60 of those days were properly chargeable to the Applicants (48 days ending 12-00-2010; and 12 days ending 05-03-2010). The other 103 days charged against the Applicants all related to the vacated Office actions. Because those actions have been vacated for purposes of PTA, it was not proper to charge the Applicants with the 30 + 42 + 31 days of delay set forth in the Office's preliminary calculation. Applicants should not be charged with delay in responding to vacated (void) Office actions.

#### **V. Terminal Disclaimer and Overlap**

This application is not subject to a terminal disclaimer. Analysis of overlap between "A delay" and "B delay" is premature because the Office has not yet calculated "B delay." However, the Applicants acknowledge that some portion of the "A delay" under 37 CFR 1.702(a)(1) that occurred more than three years after the commencement of national phase may overlap with "B delay" and not be entitled to double credit. The "A delay" that accrued on account of delayed mailing of a notice of allowance occurred after the filing of an RCE and does not overlap with "B delay" for this reason.

## **VI. Summary**

For reasons set forth below, the proper calculation of PTA, prior to analysis of “B delay” and A/B overlap and delay under 37 CFR 1.702(a)(4), should be  $(906 + 37) - 60 = 883$  days. Acknowledgement of this measure of PTA is requested.

Dated: August 16, 2011

Respectfully submitted,

By /David A. Gass #38,153/

David A. Gass

Registration No.: 38,153

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive

6300 Willis Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant